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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,305	10/31/2003	James Kaput	Kaput-100 US	5444

39843 7590 02/07/2008

BELL & ASSOCIATES
201 WARREN DRIVE
SAN FRANCISCO, CA 94131

EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	10/700,305	KAPUT, JAMES	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Bradley L. Sisson*. (3)_____.

(2) *Adam Bell, Ph.D., J.D.*. (4)_____.

Date of Interview: *01 February 2008*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *Draft claims submitted via email 2/1/2008; copy attached*.

Claim(s) discussed: *1, 4, 18, and 21*.

Identification of prior art discussed: *US Patent 6,020,143 (St. George-Hyslop et al.); US Patent 6,384,087 B1 (Zemel et al.); and US Patent 6,426,340 B1 (Gibson et al.)*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

B. L. Sisson
Examiner's signature, if required

Continuation of Substance of Interview including description of the general nature of what was agreed to if any agreement was reached, or any other comments: Mr. Sisson acknowledged receipt of the draft claims of 01 February 2008. Mr. Sisson indicated that possible issues under 35 USC 103(a) may exist. The disclosures of St. George-Hyslop et al. (column 17, 49, 53, 55, and 60-61); Zemel (column 5, and 8-9), and Gibson (Fig. 1, and cols. 2, 4, and 5) were discussed. Mr. Sisson noted that the prior art clearly taught of looking for changes in levels of expression between both normal and disease genotypes, that the animal models can be rodents, that the genes of interest can be diet regulated, that an animal model was known where it has normal levels of expression except when subjected to certain diets, and that dietary studies have been conducted where cohorts of multiple genotypes have been subjected to different diets, and levels of mRNA production analyzed.
Dr. Bell indicated that he will discuss with his client the possibility of further limitations that will render the claims non-obvious.

Sisson, Bradley

From: Adam Warwick Bell [abell@bell-iplaw.com]
Sent: Friday, February 01, 2008 4:46 PM
To: Sisson, Bradley
Cc: abell@bell-iplaw.com
Subject: Re: Response for James Kaput 10/700,305

Attachments: DRAFT AS SENT 1 FEBURARY - Kaput ROA .DOC

DRAFT AS FEBURARY

Bradley:

Here is the latest un-official draft.

I have addressed US Patent No. 5,612,486 in the remarks. I assume you can make this patent or record and no longer need a reference for Alzheimer's disease.

The mouse model for obesity and diabetes is described in Para 83 of the application: "Since Avy/A become obese (~60g v ~25g for A/a mice) and develop symptoms of Type II diabetes....." So I assume that you will not need another reference from Jim.

I have found dozens of references to mouse models for diseases (Cardiovascular, Alzheimer's and cancer). I think these show that mouse models were available for cancer long before the priority date (Nov 2002), Do you still want Jim to send you more references or will these do?

Paigen et al., 1994, "The mouse as a model for human cardiovascular disease and hyperlipidemia", Curr. Opin. Lipidol. 5:258-264.

Popovic et al., 1996, "Behavioral and adaptive status in an experimental model of Alzheimer's disease in rats", Int. J. Neurosci.

Johnson-Wood et al., 1997, "Amyloid precursor protein processing and A beta42 deposition in a transgenic mouse model of Alzheimer disease", Proc. Natl. Acad. Sci. USA 94:1550-1555.

Donehower, 1996, "The p53-deficient mouse: a model for basic and applied cancer studies", Semin. Cancer. Biol. 7:269-278.

Amundadittir et al., 1996, "Transgenic mouse models of breast cancer", Breast Cancer Res. Treat. 39:119-135.

Dankort and Muller, 1996, "Transgenic models of breast cancer metastasis", Cancer Treat. Res. 83:71-88.

Adam Warwick Bell, BSc. DPhil. JD.
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San Francisco,
California 94127

Tel: (415) 752-4085
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--- abell@bell-iplaw.com wrote:

From: "Adam Warwick Bell" <abell@bell-iplaw.com>
To: <bradley.sisson@uspto.gov>
Cc: <abell@bell-iplaw.com>, <mkaser@bell-iplaw.com>
Subject: Response for James Kaput 10/700,305
Date: Thu, 31 Jan 2008 17:09:57 -0800

Bradley:

If you received the last email, please delete this one. It is a duplicate. I was not sure whether I wrote .gov or .com on the other email.

James Kaput
Application No.: 10/700,305
Filed: 31 Oct 2003
For: IDENTIFICATION OF DIET-REGULATED DISEASE-ASSOCIATED GENES

Give me a call/email any time.

Adam

Adam Warwick Bell, BSc. DPhil. JD.
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I hereby certify that this correspondence is being emailed to Bradley.sisson@uspto.gov on 1 Feb 2008 by ADAM W. BELL (abell@bell-iplaw.com)

PATENT
Attorney Docket No.: Kaput-001US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

James Kaput

Application No.: 10/700,305

Filed: 31 Oct 2003

For: IDENTIFICATION OF DIET-REGULATED DISEASE-ASSOCIATED GENES

Examiner: SISSON

Technology Center/Art Unit: 1634

RESPONSE

UNOFFICIAL DRAFT
not to be entered

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

1 February 2008

Dear Examiner Sisson:

In response to the office action/communications mailed 10/02/07, please accept the enclosed papers and consider the following remarks.

NOTE: PLEASE NOTE NEW ADDRESS on last page of document.

FULL LISTING OF THE CURRENT PENDING CLAIMS

1. (**Currently amended**) A method for identifying diet-regulated disease-associated polynucleotides comprising the steps of:

(i) selecting a cohort from each of ~~at least~~ two different inbred rodent ~~known mammalian~~ genotypes (A and B) all of the same generation and all either male or virgin female, one of these genotypes (A) being susceptible to a disease, and the other genotype (B) not susceptible to the same disease;

(ii) dividing each ~~genotype~~ cohort into two groups (A1 and A2 and B1 and B2);

(iii) for each ~~genotype~~ cohort, each group is fed a different diet (A1 is fed diet No.1 and A2 is fed diet No.2, and similarly for B1 and B2);

(iv) measuring gene expression and comparing expression across the ~~strains~~ individuals that differ in either genotype or in diet, but not in both;

(v) analyzing the expression data so as to identify ~~diet-regulated disease-associated genes~~ in the disease-susceptible strain one or more genes that shows at least a two-fold increase or decrease in gene expression;

(vi) matching the genes shown above to have at least a two-fold increase or decrease in gene expression with one or more independently-derived quantitative trait loci (QTLs) known to encode one or more genes that contribute to the development of a disease,

(vii) wherein the genes so identified are considered to be a diet-regulated disease-associated genes.

2-3. (**Cancelled**)

4. (**Currently amended**) The method of claim [[2]] 1 wherein gene expression is compared by comparing mRNA abundance.

5-16. (**Cancelled**)

17 (**New**) The method of claim 1 wherein gene expression is compared expression across individuals that differ in genotype only.

18. (**New**) The method of claim 1 wherein gene expression is compared expression across individuals that differ in diet only.

19. (**New**) The method of claim 1 wherein the one or more independently-derived quantitative trait loci is known to encode one or more genes that contribute to diabetes.

20. (**New**) The method of claim 1 wherein the one or more independently-derived quantitative trait loci is known to encode one or more genes that contribute to obesity.

21. (**New**) The method of claim 1 wherein the one or more independently-derived quantitative trait loci is known to encode one or more genes that contribute to Alzheimer's disease.

22. (**New**) The method of claim 1 wherein the one or more independently-derived quantitative trait loci is known to encode one or more genes that contribute to a cardiovascular disease.

23. (**New**) The method of claim 1 wherein the one or more independently-derived quantitative trait loci is known to encode one or more genes that contribute to cancer.

REMARKS/ARGUMENTS

On February 1 2008, Examiner Sisson and the applicant's representative, Adam Bell, discussed the application. One of this items discussed was United States Patent 5,612,486 "Transgenic animals harboring APP allele having Swedish mutation") to McConlogue et al. This patent describes a rodent model for Alzheimer's disease. For the record, the applicant believes that this disclosure is not relevant to patentability as it does not describe or suggest certain key elements of the claims, including, in particular, dividing the cohorts into two groups, feeding each a different diet and measuring gene expression and comparing expression across the individuals that differ in either genotype or in diet, but not in both. Neither does it suggest of describe matching the genes identified with quantitative trait loci. The applicant believes that these features are entirely novel.

Claims 1-16 are pending.
Claims 2-3 and 5-16 are cancelled with entry of this amendment.
Claims 17-23 are newly added with entry of this amendment.
Claims 1 and 4 are amended with entry of this amendment.

The substantive differences presented here are related to the amendments, in which the claims are amended to recite methods using rodent strains, all of the same generation and all either male or virgin female, and wherein expression data is analyzed to identify genes in the disease susceptible strain wherein a gene that shows at least a two-fold increase or decrease in gene expression. Claim 1 has additionally been amended to incorporate the limitations of claim 2 (now cancelled) requiring that genes show to have at least a two-fold change in gene expression are matched with one or more independently-derived quantitative trait loci (QTLs) known to encode one or more genes that contribute to the development of a disease.

It is hoped that these amendments overcome the outstanding rejections.

Most of the present rejections are identical to those presented earlier, and most of the applicant's rebuttals are also identical to those previously presented, so attention is directed to the previous office action response. The substantive differences presented here are related to the amendments.

Applicant has carefully considered the rejections, has discussed the matter with the examiner and has amended and narrowed the claims in view of the outstanding rejections. It is believed that the present claim limitations overcome the current 35 USC 112 rejections for enablement and written description, and reasonably shows that the applicant was in possession of the invention at the time of filing, since the application sets out actual data performed produced using in vivo rodent experiments.

The fact that the QTL's are known to be associated with actual diseases is hopefully sufficient to indicate utility of the identified genes. Additionally, this together with the fact that the matched genes show significantly altered expression in the disease-susceptible animals compared to the normal animals, should provide sufficient evidence that, in rodents, these genes are diet-regulated, disease associated genes.

The limitation requiring that the rodents all be of the same generation and all either male or virgin female should overcome the issue of variability amongst individuals due to sex or age.

The limitation requiring that the identified genes have at least a two-fold increase or decrease in gene expression in response to diet hopefully removes the issue of indefiniteness with regard to the measurable nature of the change in expression.

Support for the amendments

The amendment to claim 1 is found in the original specification at:

> paragraph 77 ("Male or virgin female (eliminates complications and effects of pregnancy) mice of defined genotype are fed a semi-purified diet containing 4% corn oil for 1 wk…");

paragraph 53 ("Differential gene expression is identified between the compared groups, and genes are identified that show significant changes in expression (e.g., a 1.5 or 2.0 or 2.5 –fold increase or decrease in gene expression…");

paragraph 29 ("Genetic methods for identifying quantitative trait loci … have been developed over the past 15 years. Such methods identify regions of chromosomes encoding one or more genes that contribute to the development of a complex disease, e.g., diabetes");

and in originally filed claim 2.

Support for new claims 17 and 18 is found in claim 1. New claims 17 and 18 simply recite a narrower embodiment of claim 1.

Support for new claims 19 to 23 is found at:

paragraph 29 ("Approximately 1700 QTLs for diabetes, obesity, cancer, and other conditions have been determined in laboratory animals and a smaller subset has been identified in humans.";

paragraph 9 ("Chronic diseases, including obesity, Alzheimer's, diabetes, cardiovascular diseases, and certain cancers (among others), are generally produced by the interplay of environmental factors and genetic mechanisms.");

and paragraph 23 ("Similar strategies of identifying known pathways, known genes, and known enzymes as drug targets are used for almost all major diseases including Alzheimer's, cancer, diabetes, and obesity.").

No new matter is added by these amendments.

James Kaput, the applicant and inventor, will soon be sending a short list of publications that pre-date the priority date of this case, and that describe rodent models for various diseases. We will ask that these references be entered into the record.

CONCLUSION

In view of the above reasoning, it is hoped that the claims are now in a condition for allowance.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-752-4085.

Deposit Account

The Commissioner is hereby authorized to charge any calculated fee or any additional fees associated with this communication in particular and this application in general, and to credit any overpayment to Bell & Associates Deposit Account No. 50-3194

Respectfully submitted,

THIS IS A DRAFT DOCUMENT FOR DISCUSSION
[NO SIGNATURE]

Adam W. Bell, Reg. No. 43,490
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Sisson, Bradley

From: Adam Warwick Bell [abell@bell-iplaw.com]
Sent: Friday, February 01, 2008 6:22 PM
To: Sisson, Bradley
Subject: Fwd: Scientific papers from Jim Kaput
Attachments: paper

Bradley:

Jim sent me these papers.

They show rodent models for obesity, diabetes, cancer, cardiovascular disease and cancer, ane they were all publiched before our priority date!

I am happy to authorize you to make any minor examiner's amendments you think would result in allowable claims.

Many thanks,

Adam

PS: Here is the link to my hime to Everest. I highly recommend it!
http://picasaweb.google.com/warwickbell/NepalKumbu2007

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Sisson, Bradley

From: Jim Kaput [jkaput@gmail.com]
Sent: Friday, February 01, 2008 6:04 PM
To: Adam W. Bell
Subject: paper
Attachments: Breslow_PNAS_90_8314_93_transgenic_athero.pdf; Donehower_SCB_7_269_96_Cancer.pdf; Hakem_JMGBN_3_431_98_BRCA1_Cancer_model.pdf; Johnson_Wood_PNAS_94_1550_97_Alzheimers.pdf; Koya_FASEB_14_439_00_diabetes.pdf; Uysal_Endocrinology_141_3388_00_Obese_aP2.pdf

here they are

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